

COMPOSITION AND METHOD FOR RECTAL DELIVERY OF A  
LINCOSAMIDE ANTIBIOTIC DRUG

CROSS REFERENCE TO RELATED APPLICATIONS

- 5 The present patent application is a continuation-in-part of U.S. Patent  
 Application Serial No. 09/619,930, filed July 20, 2000, <sup>now U.S. Patent No. 6,495,157</sup> that claims the benefit of U.S.  
 Provisional Patent Application Serial No: 60/147561, filed August 6, 1999.

FIELD OF THE INVENTION

- 10 The present invention relates to a pharmaceutical composition useful for rectal  
 application for treatment or prevention of infective disease. In particular, the present  
 invention relates to a rectal formulation of a lincosamide antibacterial drug that can be  
 used for treatment or prevention of infection by a gram-positive bacterial agent. The  
 field of the present invention also includes therapeutic or prophylactic use of such a  
 formulation, and use of such a formulation in preparation of a medicament.

15 BACKGROUND OF THE INVENTION

- Lincosamide compounds have been reported having therapeutically and/or  
 prophylactically useful antibiotic, in particular antibacterial, effect. Lincosamides,  
 such as clindamycin, lincomycin, and pirlimycin, have long been recognized as  
 antibiotics active against bacteria, primarily, against gram-positive bacteria.  
 20 Lincosamides are known to prevent translocation of nascent polypeptide, making the  
 class of compounds useful for the treatment of a variety of disorders related to  
 bacterial infections.

- Clindamycin has long been recognized as being particularly effective in the  
 treatment of staphylococcal infections. Several commercial formulations of  
 25 clindamycin designed for oral administration can be found on the market, including  
 CLEOCIN<sup>®</sup> HCL (Pharmacia Corporation, NJ, USA), an oral formulations of  
 clindamycin hydrochloride designed for adults, and CLEOCIN<sup>®</sup> PEDIATRIC  
 (Pharmacia Corp.), an oral formulation of clindamycin palmitate hydrochloride  
 designed for children. In such formulations clindamycin hydrochloride and